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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/594,735	09/29/2006	Valerie Andre	12810-00346-US1	1588
23416 7590 03/25/2009 CONNOLLY BOVE LODGE & HUTZ, LLP P O BOX 2207			EXAMINER	
			FRAZIER, BARBARA S	
WILMINGTON, DE 19899		ART UNIT	PAPER NUMBER	
			1611	
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			03/25/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)				
	10/594,735	ANDRE ET AL.				
Office Action Summary	Examiner	Art Unit				
	BARBARA FRAZIER	1611				
The MAILING DATE of this communication app Period for Reply	ears on the cover sheet with the c	orrespondence address				
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).						
Status						
1)⊠ Responsive to communication(s) filed on <u>05 Ja</u>	nuary 2009 and 25 February 200	09				
·= · · · · · · · · · · · · · · · · · ·	•					
3) Since this application is in condition for allowan		secution as to the merits is				
	closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.					
Disposition of Claims						
4)⊠ Claim(s) <u>1-20</u> is/are pending in the application.						
4a) Of the above claim(s) <u>3-11 and 13-20</u> is/are withdrawn from consideration.						
5) Claim(s) is/are allowed.						
6)⊠ Claim(s) <u>1,2 and 12</u> is/are rejected.						
7) Claim(s) is/are objected to.						
8) Claim(s) are subject to restriction and/or	election requirement.					
Application Papers						
9)☐ The specification is objected to by the Examiner.						
10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.						
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).						
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.						
Priority under 35 U.S.C. § 119						
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of:						
1. Certified copies of the priority documents have been received.						
 2. Certified copies of the priority documents have been received in Application No 3. Copies of the certified copies of the priority documents have been received in this National Stage 						
application from the International Bureau (PCT Rule 17.2(a)).						
* See the attached detailed Office action for a list of the certified copies not received.						
dee the attached detailed office action for a list of the certified copies not received.						
Attachment(s)						
1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s)/Mail Date						
3) Information Disclosure Statement(s) (PTO/SB/08) 5) Notice of Informal Patent Application						
Paper No(s)/Mail Date 6) Other:						

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DETAILED ACTION

Status of Claims

1. Claims 1-20 are pending in this application.

- 2. Claims 3-11 and 13-20 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 1/24/08.
- 3. Claims 1, 2, and 12 are examined.

Claim Rejections - 35 USC § 103

- 4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
- 5. Claims 1, 2, and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tanner et al (US Patent 5,827,508) in view of Meguro et al (US Patent 4,640,943) and Mazo et al (US Patent 5,939,518).

The claimed invention is drawn to a surface-modified nanoparticulate metal oxide, wherein the surface modification comprises a coating with polyasparaginic acid with a molecular weight $M_{\rm w}$ of from 1000 to 7000, and the metal oxide particles have an average primary particle diameter of from 10 to 200 nm (see claim 1).

Tanner et al teach compositions having enhanced stability that are useful for protecting human skin from the harmful effects of UV radiation, comprising a surface-

treated zinc oxide (see col. 2, lines 48-56). The surface-treated zinc oxides have a mean particle size preferably from about 0.01 to about 10 microns (i.e., from about 10 to about 10,000 nm), and more preferably from about 0.01 to about 2 microns (i.e., from about 10 to about 2,000 nm) (see col. 6, lines 36-42). This particle size range encompasses that of the claimed invention; one skilled in the art would be motivated to select particle size from within said ranges by routine experimentation, in order to optimize properties of the resultant particle, such as stability and flowability. The surface treatment materials useful for treating the zinc oxide particles include amino acids (col. 6, lines 65-67).

Tanner et al do not specifically teach that the amino acid is polyasparaginic acid.

Meguro et al teach that surface modifiers such as polyaspartic acid are known in the art to be used for the purpose of improving the wettability and enhancing the dispersibility of inorganic fillers such as oxides of titanium, zinc, and iron (see col. 2, lines 3-6 and 17, and col. 1, lines 13-18). The metal oxides may be used in cosmetic formulations (col. 1, lines 37-39).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to select the polyaspartic acid surface modifier taught by Meguro et al as the amino acid surface treatment material of Tanner et al, thus arriving at the claimed invention. One skilled in the art would have been motivated to do so because the use of polyaspartic acid as the amino acid surface modifier provides the benefits of improving the wettability and enhancing the dispersibility of the metal oxide, as taught by Meguro et al. One would reasonably expect success from the use of

polyaspartic acid taught by Meguro et al with the metal oxides taught by Tanner et al because both references are drawn to the use of surface-treated metal oxides in cosmetic formulations.

Meguro et al is silent with respect to the specific molecular weight of the polyaspartic acid.

However, Mazo et al teach that polyaspartates are becoming increasingly useful as additives for cosmetics and personal care products (col. 1, lines 14-17), and having "desired high molecular weight" (col. 1, lines 41-42). The polyaspartates are prepared by hydrolyzing polysuccinimides (col. 3, lines 8-10), which have a weight average molecular weight (M_w) in the range of about 3,000 to about 40,000 (col. 3, lines 39-41). Therefore, the M_w of the polyaspartates would be comparable to that of the polysuccinimides (i.e., about 3,000 to about 40,000).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to select the molecular weight of the polyaspartic acids taught in Mazo et al for the polyaspartic acid surface modifiers of Mazo et al. One skilled in the art would have been motivated to do so because high molecular weights of polyaspartic acid are desired as dispersants and additives for cosmetics and personal care products, as taught by Mazo et al. Additionally, the molecular weight range taught by Mazo et al overlaps that of the claimed invention; one skilled in the art would be motivated to select molecular weight of polyaspartic acid from within said ranges by routine experimentation, in order to optimize properties of the polyaspartic acid, such as dispersibility. A skilled artisan would reasonably expect success from the selection of

the polyaspartic acids of Mazo et al for the polyaspartic acid surface modifiers of Meguro et al because both compositions are drawn to using polyaspartic acid in cosmetics and personal care products.

With respect to claim 2, Tanner et al teach a surface-treated zinc oxide (col. 2, lines 55-56).

With respect to claim 12, Tanner et al teach that the compositions of the present invention are useful for providing protection to human skin from the harmful effects of UV radiation (col. 15, lines 34-36), and may include other cosmetic ingredients (col. 14, lines 54-62).

Response to Arguments

6. Applicant's arguments filed 1/5/09 and 2/25/09 have been fully considered but they are not persuasive.

Applicant's arguments with respect to monomeric units of dimethicone vs. elemental silicon are duly noted. While this argument was made was merely to point out that the term "amino acids" is not limited to just the monomers, this portion of the response to applicant's arguments (dated 9/5/08) is withdrawn. However, the claims are still rendered obvious for reasons stated above and in the following response to arguments.

Applicants also argue that polyasparaginic acid and aspartic acid are very different in many properties, and simply because aspartic acid can be polymerized is insufficient for a finding of support of polyasparaginic acid in Tanner which only

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suggests the monomer. Applicants also argue that Tanner suggests using silicones, such as dimethicone, as a preferred coating for nano-particular zinc oxide, and that Tanner fails to suggest using a polyaspartic acid coating to decrease the particle size of the zinc oxide particles, especially that there is no suggestion of using polyaspartic acid for manufacturing zinc oxide particles in the range of from 10 to 200 nm.

This argument is not persuasive because Tanner et al teach that "nonlimiting classes" of surface treatment materials includes "amino acids", and "amino acids", as a class, are not limited to just its monomers. Additionally, while Tanner does teach the use of dimethicone as a preferred coating, it also clearly teaches that amino acids may also be used as a surface treatment material (col. 6, lines 65-67); disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. In re Susi, 440 F.2d 442, 169 USPQ 423 (CCPA 1971). Moreover, the rejection is not based on Tanner et al alone, but rather on the combined teachings of Tanner with Mazo and Meguro, which clearly points out that polyaspartic acid is a known surface modifier of inorganic fillers, such as zinc oxide (col. 2, lines 3-17 and col. 1, lines 13-17). In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., that the polyaspartic acid coating is used to decrease the particle size of the zinc oxide particles) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Nevertheless, it is pointed out that Tanner does teach

that the surface-treated zinc oxides have a mean particle size preferably from about 0.01 to about 10 microns (i.e., from about 10 to about 10,000 nm), and more preferably from about 0.01 to about 2 microns (i.e., from about 10 to about 2,000 nm) (see col. 6, lines 36-42). This particle size range encompasses that of the claimed invention; one skilled in the art would be motivated to manipulate the size of the particles from within said ranges by routine experimentation, in order to optimize properties of the resultant particles, such as stability and flowability.

Applicants also argue that Meguro, at col. 2, lines 39-47, teaches away from using polymers for surface modification, because Meguro suggests that polymer coats on inorganic substances can swell or dissolve and separate from the surface.

This argument is not persuasive because, at col. 2, lines 39-47, Meguro is referring to polymers **such as polystyrene** (emphasis added), and does not teach that polyaspartic acid encounters the same problems. Furthermore, Meguro only teaches that said problems are possible (not definite) depending on the solvent used, and therefore would limit the type of solvent used. Limiting the solvent with polymers such as polystyrene is not a clear teaching away from the use of polyaspartic acid altogether.

Applicants also argue that Meguro's coated inorganic pigments and fillers are of a much bigger size than the metal oxide particles in accordance with claim 1, since Meguro describes a coating process for pigment and fillers having an average particle size of 0.1 to 100 um.

This argument is not persuasive because it is the background information taught in Meguro that is relied upon, not the process of its instant invention. The teachings of

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Meguro are relied upon to show that it is known in the art to use polyaspartic acid as a surface modifier for inorganic fillers, such as zinc oxide. Even so, the Examiner points out that 0.1 to 100 um is the same as 100 to 100,00 nm; this size range overlaps that of the claimed invention, and therefore one skilled in the art would reasonably expect the teachings of Meguro to apply to the claimed invention.

Applicants also argue that Meguro uses the terms "pigment" and "filler", as a component in "makeup cosmetic", and Meguro enumerates the cosmetic composition in which the coated pigments or fillers are being used at col. 6, lines 62-68.

It is not clear what Applicants are arguing here; if Applicants are trying to distinguish Meguro from Tanner by asserting that the use of the compositions of Meguro is limited to cosmetics, it is pointed out that Tanner also teaches that its compositions are included in cosmetic type products as well (see col. 1, lines 51-53).

Applicants also argue that there is no suggestion in Meguro for the use of inorganic particles of sufficiently small size to enable the preparation of transparent cosmetic compositions.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the preparation of transparent cosmetic compositions) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Applicants also argue that Mazo suggests that polysuccinimide, polyaspartates and copolymers thereof are useful, for example, as lubricants for conveyor belts, and that Mazo fails to suggest that the molecular weights are desirable for a polyasparaginic acid coating of a metal oxide nanoparticle, as claimed. Applicants also argue that the data in Table II of Mazo is not a suggestion of using polyaspartic acid with a molecular weight in the range of 1000 to 7000 for the manufacture of coated nano-particular metal oxides.

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This argument is not persuasive because Mazo et al clearly teach that polyaspartates have utility as additives for cosmetics and personal care products (col. 1, lines 14-17), and therefore one skilled in the art would look to the teachings of Mazo for guidance regarding desirable molecular weights for polyaspartates in cosmetics and personal care products, such as in Tanner et al. Regarding the molecular weights of polyaspartates, it is pointed out that, while the molecular weights in Table II are referring to polyaspartates, Mazo also teaches that the polyaspartates are prepared by hydrolyzing polysuccinimides (col. 3, lines 8-10), which have a weight average molecular weight (M_w) in the range of about 3,000 to about 40,000 (col. 3, lines 39-41). Therefore, the M_w of the polyaspartates would be comparable to that of the polysuccinimides (i.e., about 3,000 to about 40,000). This molecular weight range overlaps that of the claimed invention; one skilled in the art would be motivated to select molecular weight of polyaspartic acid from within said ranges by routine experimentation, in order to optimize properties of the polyaspartic acid, such as dispersibility.

Applicants also present experimental results in their response and assert that said results "underline the unexpected and advantageous effect of using polyaspartic acid of the molecular weight as claimed compared to coatings with polyaspartic acid higher molecular weight."

This data has been reviewed but is not persuasive for overcoming the rejection because 1) the data is not presented in declarative form, 2) Applicants have not correlated the data with any unexpected or advantageous effect, and 3) one skilled in the art would reasonably expect polyaspartic acid of higher molecular weight (g/mol) to result in particles of increased particle size.

7. Claims 1 and 2 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kropf et al (US 2004/0033270) in view of Mazo et al (US Patent 5,939,518).

The claimed invention is delineated above (see paragraph 5).

Kropf et al teach hygiene products produced using zinc oxide in the form of nanoparticles having surfaces that have been modified using organic compounds such as amino acids (abstracts). The particularly preferred average primary particles size of the zinc oxide nanoparticles is 5 to 20 nm, 10-25 nm or 15-35 nm (paragraph 14). The surface modifier may be polyaspartic acid (paragraph 48).

Kropf et al is silent with respect to the specific molecular weight of the polyaspartic acid.

However, Mazo et al teach that polyaspartates are becoming increasingly useful as additives for cosmetics and personal care products (col. 1, lines 14-17), and having

"desired high molecular weight" (col. 1, lines 41-42). The polyaspartates are prepared by hydrolyzing polysuccinimides (col. 3, lines 8-10), which have a weight average molecular weight (M_w) in the range of about 3,000 to about 40,000 (col. 3, lines 39-41). Therefore, the M_w of the polyaspartates would be comparable to that of the polysuccinimides.

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to select the molecular weight of the polyaspartic acids taught in Mazo et al for the polyaspartic acid surface modifiers of Kropf et al. One skilled in the art would have been motivated to do so because high molecular weights of polyaspartic acid are desired as dispersants and additives for cosmetics and personal care products, as taught by Mazo et al. Additionally, the molecular weight range taught by Mazo et al overlaps that of the claimed invention; one skilled in the art would be motivated to select molecular weight of polyaspartic acid from within said ranges by routine experimentation, in order to optimize properties of the polyaspartic acid, such as dispersibility. A skilled artisan would reasonably expect success from the selection of the high molecular weight polyaspartic acids of Mazo et al for the polyaspartic acid surface modifiers of Kropf et al because both compositions are drawn to using polyaspartic acid in cosmetics and personal care products.

Regarding claim 2, Kropf et al teach surface modified zinc oxide (see abstract).

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Response to Arguments

8. Applicant's arguments filed 1/5/09 and 2/25/09 have been fully considered but they are not persuasive.

Applicants argue that Kropf suggests that zinc oxide is modified with stearic acid. Applicants also argue that Kropf is specifically not directed to a coating, as claimed, since the surface modifiers disclosed therein are not coatings in the sense that the nano-sized particles are completely covered, but that Zn ions can be released into the surrounding area (in other words, Kropf suggests vehicles that allow distribution of zinc ions into the hygienic product).

This argument is not persuasive because stearic acid is only one example of surface modifiers which can be used; Kropf clearly teaches that polyaspartic may also be used as a surface modifier (see paragraph 48). Additionally, Kropf still teaches "the coating of the particle surface" (see paragraph 39), and therefore still falls within the definition of the term "coating", albeit without completely covering the particle.

Applicants also argue that Kropf does not recognize any benefits of using polyaspartic acid having a molecular weight Mw of from 1000 to 7000 or that use of polyaspartic acid with that molecular weight results in the production of coated particles with an average particle size of less than 200 nm, as set forth in the table in Applicant's response.

This argument is not persuasive because Kropf still fairly teaches and suggests the use of polyaspartic acid as a coating and the required particle size of the zinc oxide, such as 10-25 nm or 15-35 nm (see paragraph 14). Furthermore, the rejection is not

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based upon Kropf alone, but rather on the combined teachings of Kropf and Mazo, which teaches that desirable molecular weights for polysuccinimide and its hydrolysis product, polyaspartate, are from 3,000 to 40,000 (col. 3, lines 39-41). The molecular weight range taught by Mazo et al overlaps that of the claimed invention; one skilled in the art would be motivated to select molecular weight of polyaspartic acid from within said ranges by routine experimentation, in order to optimize properties of the polyaspartic acid, such as dispersibility.

Applicants also argue that there is no suggestion or rationale set forth in Mazo to use polyaspartate with a specific molecular weight for nanoparticulate metal oxides, and that Mazo fails to suggest that a particular molecular weight is preferable for any particular application.

This argument is not persuasive because Mazo teaches that polyaspartates are useful as additives for cosmetics and personal care products, and therefore one skilled in the art would look to the teachings of Mazo for guidance regarding the molecular weight of polyaspartates in cosmetic and personal care products, such as those taught in Kropf et al, or Tanner et al and Meguro et al.

Examiner's Remarks

9. It is noted that the status identifier for claim 12 currently reads, "Withdrawn". Since this claim is not withdrawn, Examiner suggests changing the status identifier to "Previously Presented", to reflect its current status.

Conclusion

No claims are allowed at this time.

10. Applicant's amendment necessitated any new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BARBARA FRAZIER whose telephone number is (571)270-3496. The examiner can normally be reached on Monday-Thursday 9am-4pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on (571)272-0614. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BSF

/Lakshmi S Channavajjala/ Primary Examiner, Art Unit 1611 March 23, 2009